

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
RICHMOND DIVISION

MONICA L. BALL,

Plaintiff,

V.

Case No. 3:13-cv-168

TAKEDA PHARMACEUTICALS
AMERICA, INC., et al.,

Defendants.

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR
RELIEF UNDER F.R.C.P. 60(b) TO REVERSE THE COURT'S ORDER OF
DISMISSING THE COUNTS OF FRAUD AND EXPRESSED WARRANTY FROM THE
PLAINTIFF'S COMPLAINT**

Plaintiff respectfully request that the Court to grant her relief under F.R.C.P. 60(b).

As set forth in the attached Declaration of Jerrod M. Smith, plaintiff's counsel filed an opposition to the Defendants' memorandum of a motion to dismiss the complaint in regards to expressed warranties, and fraud, and now the Plaintiff is requesting relief under F.R.C.P. 60(b) due to the Defendants' were involved in litigation concerning misinformation given to the FDA concerning the Dexilant medication, and one of the allegations made was that Takeda a foreign corporation misled physicians and patients in believing that 60mg Dexilant tablets were safe to treat GERD, which Plaintiff Ball had, when the FDA only approve 30mg tablet for the treatment of GERD.

Further, Plaintiff asked for the complete information in discovery, and the Defendants have failed in providing Admissions, and answers to interrogatives and have failed to provide the demand for documents.

Plaintiff uncovered the information and believe it is timely in requesting of this court to have the order dismissing the fraud, and expressed warranties be over turned and the Plaintiff allowed to amend the complaint to include the present claims, as well as the fraud and expressed warranties. The fact that the Defendants did not list Stevens Johnson Syndrome in the expressed warranties listed in the 2010 Physicians' Desk Reference, nor in the 2011 Physicians' desk reference is significant.

Further, the Defendants failed to answer these simple admissions which would aid her non-medical and her medical experts. Defendant were specifically asked for the information related to the whistleblower claims that the United States brought against them, and the Defendants have refused to provide the information related to the Dexilant 60mg versus the 30mg approval of the FDA to treat GERD.

The issues of fertility are fluid just as the injuries that are incurred.

Defense counsel stood before this Court and stated that the Plaintiff's allegations which included fraud were only conclusory and and speculative allegations all the while knowing that his client had been sued on the very issues of fraud and misrepresentation to the FDA.

MR. WRIGHT: Understood. Okay.

Well, Your Honor, with all the redundancy in the complaint, and the conclusory allegations and speculative allegations, what plaintiff, I think, is trying to allege is simply a failure to warn claim. That is what it boils down to. We know that when the case was, the earlier case was filed, the focus was on Steven-Johnson, Your Honor.

THE COURT: Well, injuries are fluid.

MR. WRIGHT: YES. (See Transcript of April 26, 2013, page 4, line 13-22).

The Plaintiff respectfully states that this not only mischaracterizes the fact that both Stevens Johnson and impaired fertility were two separate claims in the complaint, but the Defendants go on to make further arguments for dismissal with the knowledge of the allegations regarding misrepresentation of Dexilant, by Takeda, to the FDA, physicians and patients regarding the dosage for treatment of GERD.

Mr. Wright made these allegations against the complaint that Plaintiff submitted with counts of fraud, yet already knowing that the Whistleblower claim was being litigated by the United States. The United States and the whistleblowers had issues with the Defendants Takeda making misrepresentations to the FDA about Dexilant, and misinforming the physicians about the dosage to treat GERD which Plaintiff Monica Ball had before she incurred her injuries.

Plaintiff still respectfully contends that both infertility and Stevens Johnson Syndrome failure to warn were in the the complaint. Further, Defense counsel presents to this Court the Defendant's stance regarding the information provided for Dexilant.

THE COURT: Are Dexilant research studies on the side effects of Dexilant, or sorry, Takeda's research studies on the side effects of Dexilant, are they available to the public?

MR. WRIGHT: They are – I do not believe they are available to the public. They are provided to the FDA. Perhaps with a FOIA request you could get them from the FDA.

THE COURT: But not generally available. I couldn't go to the library and look at them.

MR. WRIGHT: That is right. They are described in summary form, as you know, in the warning materials. (See Transcript of April 26, 2013 page 8, lns 8-19).

The Defense counsel also stated to this Court the issue of fraud in its argument to dismiss the Plaintiff's count of fraud.

The Defendants counsel statement on fraud during the hearing on April 16, 2013 is as follows.

MR. WRIGHT:If the Court looks – Court's indulgence. In America Chiropractic case, Your Honor—that is 367 F 3d 212 – the court explained that “American Chiropractic explicitly referred to ancillary professional provider agreement. And the mail and wire fraud claims are based on alleged misrepresentation made in that document. (See Transcript April 16, 2013, page 6 lns 3-9).

Defendants counsel made these statements to the court knowing that they had litigation on the issue of the Defendants misrepresenting to the FDA as well as physicians the issue of 30mg of Dexilant being approved by the FDA, and the 60mg being advertised to doctors as being safe to treat the Plaintiff GERD.

The issue of fraud is what the Defense counsel tried to stir the court from, and Defense counsel only wanted the Court to concentrate on the issue of the failure to warn. When the Defense counsel directed the court attention away from the issues of fraud, and the material breach of an expressed warranty, the Defense counsel knew of the allegations concerning the misrepresentations to the FDA and physicians by Defendants Takeda at .el.

This was known at the time the Defendant's counsel made these representations to the Court, and purposely narrowed the argument to just that of failure to warn for the most part.

Therefore, the Defense counsel using a statement made by the Plaintiff's counsel before the fluid information came into the Plaintiff's knowledge, only is applicable if litigation is found to hold a pattern in a vacuum, or in tunnel visions. However, when Defense counsel knew or should have known of the allegations of the Whistleblowers concerning the misrepresentations regarding Dexilant, it gives the court another issue to consider regarding the fluid litigation in these convoluted cases.

Plaintiff's counsel did not find the documents until after the Court in the whistleblower case removed the protective order.

In addition, in regards to the issue of the breach of expressed the prescription itself is an expressed warranty.

The Defendants did not provide information on this litigation to the Plaintiff. Plaintiff asked for such documents, yet the Defendants did not provide them in production request that the Plaintiff had submitted. Plaintiff counsel spoke with Defense counsel about the discovery as well as complying with the Court's order, but the Defense counsel refused to comply with the Court's order. Plaintiff's counsel corresponded with Defense counsel regarding the failure to make admissions, and the other discovery insufficient answers. Discovery was due to Plaintiff on July 5, 2013 in time for the information to be submitted to Plaintiff's experts. However, the Defendant did not supply full answers to the discovery.

Further, the Defendants did not supply any of the documents that the Plaintiff requested concerning material issues such as the issue of misleading the FDA in regards to the Dexilant product that was waged by former employee and the United States Government.

The entire facts surrounding the issues give rise to the Court have sufficient reasons to overturn the dismissal of the fraud and the expressed warranties and allow the Plaintiff to submit a new motion to Amend the complaint, and memorandum.

Defendants knew when they asked this court to dismiss the expressed warranties, and fraud that they did not have the issue of Stevens Johnson in the Physicians' Desk Reference. As this court knows fraud is not only actual fraud, but it is also based upon negligence as well. It is a fact that the Physicians' Desk Reference does not have warnings to Physicians concerning Stevens Johnson Syndrome in the 2010 and the 2011 publications of the Physicians' Desk Reference.

Further, the Defendants had in this knowledge as well as the allegations of misrepresentation in the whistleblower case in their possession and control. The Defendants and their counsel also knew of the information that they had advertised and sold Dexilant to cure GERD using 60mg, when the FDA had only approved 30mg tablets in the treatment of the disease of GERD. Plaintiff Monica Ball suffered from GERD, and she took an overabundance of 60mg to treat GERD, when the FDA had only approve 30mg for her needed treatment. Plaintiff Monica Ball was given 60mg samples for almost 30 days, and she took this medication as prescribed. Lab test show that extreme or prolong use of the ingredients in Dexilant could cause deformities in uterus in lab experiments. Defendants withheld the information that the lawsuit was active, and failed to admit questions about the misrepresentation, and also failed to provide documents and sufficient answers to interrogatories.

Such withholding of information from this Court as well as the Plaintiff is enough information to suffices as a basis to set aside the Court's Order granting the Defendants' motion to dismiss the issue of fraud, and the count of expressed warranties under F.R.C.P. 60(b).

ARGUMENT

1. Basis of Rule 60

F.R.C.P. 60(b) sets forth the circumstances in which a court may relieve a party from what would otherwise be a final judgment. Those circumstances include “(1) mistake, inadvertence, surprise, or excusable neglect; [...] or (6) any other reason that justifies relief.” *Id.*

Motions for reconsiderations are not vehicles for relitigating old issues, or motions for “initial consideration” unless the arguments or evidence were not available earlier. *See Sigsworth v. City of Aurora*, 487 F.3d 506, 512 (7th Cir. 2007); *National Ecological Found. v. Alexander*, 496 F.3d 466, 477 (6th Cir. 2007).

However, they can be used to bring to the Court’s attention information that was misrepresented, recently discovered, negligently handled, or which was entered by mistake.

The Defendants had in their possession, but the Plaintiff did not have in her possession the information concerning the allegations of misrepresentations to the FDA and physicians regarding the Dexilant 60mg versus the 30mg dosages.

(b) Mistakes; Inadvertence; Excusable Neglect; Newly Discovered Evidence; Fraud, etc.

On motion and upon such terms as are just, the court may relieve a party or a party’s legal representative from a final judgment, order, or proceeding for the following reasons:

- (1) mistake, inadvertence, surprise, or excusable neglect;
- (2) newly discovered evidence which by due diligence could not have been discovered in time to move for a new trial under Rule 59(b);
- (3) fraud (whether heretofore denominated intrinsic or extrinsic), misrepresentation, or other misconduct

of an adverse party;

(4) the judgment is void;

(5) the judgment has been satisfied, released, or discharged, or a prior judgment upon which it is based has been reversed or otherwise vacated, or it is no longer equitable that the judgment should have prospective application; or

(6) any other reason justifying relief from the operation of the judgment. The motion shall be made within a reasonable time, and for reasons (1), (2), and (3) not more than one year after the judgment, order, or proceeding was entered or taken.

A motion under this subdivision (b) does not affect the finality of a judgment or suspend its operation. This rule does not limit the power of a court to entertain an independent action to relieve a party from a judgment, order, or proceeding, or to grant relief to a defendant not actually personally notified as provided in Title 28, U.S.C. § 1655, or to set aside a judgment for fraud upon the court. Writs of coram nobis, coram vobis, audita querela, and bills of review and bills in the nature of a bill of review, are abolished, and the procedure for obtaining any relief from a judgment shall be by motion as prescribed in these rules or by an independent action.

2. Grounds for motion

A misrepresentation to this court, or the idea of trying to move the court from an issue that the Defendants knew was at issue, is sufficient enough grounds for the court to reverse its decision to dismiss the counts of fraud and breach of expressed warranty.

Relief for the Plaintiff is necessary to ensure that the Plaintiff do not suffer because opposing counsel directed the Court from the issues of fraud and expressed warranty found in the FDA, and information to Physicians given to Plaintiffs along with the expressed warranty of the prescription, and the information on the dosage and treatment.

Plaintiff respectfully ask for a finding that the phrasing of Rule 60(b) “free[s] courts to do justice in cases in which the circumstances generally measure up to one or more itemized grounds.”)

CONCLUSION

Plaintiffs respectfully request that the Court grants and order reversing the Order to dismiss the Plaintiff’s counts of fraud and the breach of expressed warranty from the Plaintiff’s 2nd Amended Complaint, and the Plaintiff be allowed to make a motion to amend her complaint with a memorandum in support of the motion.

July 27, 2013

Respectfully submitted,

By: /s/
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 27th day of July, 2013, a copy of the foregoing was sent by electronic mail to:

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